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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,874	03/10/2004	Stephane Cotin	MGH-021AUS	5066

22494 7590 09/05/2008
DALY, CROWLEY, MOFFORD & DURKEE, LLP
SUITE 301A
354A TURNPIKE STREET
CANTON, MA 02021-2714

EXAMINER

MUSSELMAN, TIMOTHY A

ART UNIT	PAPER NUMBER
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3714

NOTIFICATION DATE	DELIVERY MODE
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09/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@dc-m.com
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Office Action Summary	Application No. 10/797,874	Applicant(s) COTIN ET AL.	
	Examiner TIMOTHY MUSSELMAN	Art Unit 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

In response to the communication filed 5/29/2008, claims 1-23 remain pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Claims 1-2, 4-9, 11-14, 16-19, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillio (US 5,704,791) in view of Pugh (2003/0031993).

Regarding claims 1, 4, 8, 12, and 16-17, Gillio discloses a surgical training device and methods of use. See col. 2: 37-55. The device comprises a base with a frame extending therefrom [**claim 1**]. See fig. 6. Gillio further discloses a first instrument tracking module coupled to the base for tracking a position of a first instrument during a training procedure performed by a user [**claims 1, 12**]. See col. 13: 40-50. Gillio further discloses wherein the apparatus can include a second instrument and tracking module [**claims 4 and 12**]. See col. 14: 1-5. Gillio further discloses a display means for generating visual feedback to the user [**claim 12**]. See col. 2: 47-55. Gillio further discloses wherein the user manipulates a simulated workpiece providing substantially realistic haptic feedback [**claims 8 and 17**]. See col. 7: 37-43. Gillio, however, although describing assessment based on position (see col. 3: 5-10), Gillio fails to *explicitly* teach of assessing the user based on comparing the user's location data to the location data of

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an expert procedure. However, this is old and well known in the art of medical simulation and testing. Pugh, for example, discloses a medical training procedure which utilizes this concept. See paragraph 50. It would have been obvious to one of ordinary skill in the art to include this feature of Pugh in the system of Gillio, because it would merely be a combination of elements known in the art and would not produce any unexpected results.

Regarding claims 2 and 23, Gillio further discloses wherein the instrument can be a full length laparoscopic instrument. See col. 14: 1-3, where it is disclosed that a full sized instrument can be used as an input, and col. 4: 23-28, where there is described an endoscopic shaft (laparoscopy is a subset of endoscopy), and additionally therein Gillio discloses simulating operations through an incision (i.e. laparoscopic surgery). Gillio further discloses, as per claim 2, wherein the first instrument can include an instrument (e.g. a laparoscopic instrument as described above), and a tracking device. See col. 15: 23-34 and col. 13: 30-40.

Regarding claim 5 and 18, Gillio further discloses wherein the system includes a data processing module to compute a score for one or more parameters based upon the position information of the first instrument over the course of the one or more training procedures. See col. 3: 5-10 and col. 18: 25-40.

Regarding claims 6, 14, and 19, Gillio further discloses at least one parameter processing module pertaining to response orientation (i.e. position). See col. 3: 5-10.

Regarding claim 7, Gillio further discloses wherein the first instrument tracking system includes sensors to track an instrument in first, second, and third axes and rotation about an axis of the first instrument. See col. 9:57 – col. 10:19.

Regarding claim 9, Gillio further discloses a platform to support the training object. See fig. 6, label 314. Note that although the simulated model, although not shown explicitly resting on a platform, must be

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supported by some manner of a platform since it cannot be suspended in space. Whether set on the bottom of the box, or supported by attaching means to the top or sides, the structure that supports the model is a platform.

Regarding claims 11 and 22, Gillio further discloses a visual feedback system coupled to the frame. See col. 5: 45-50 and fig. 6.

Regarding claim 13, Gillio further discloses a database to store instrument position information for the training task. See col. 17: 36-46.

Regarding claim 20, Gillio discloses performance evaluation features as described above, but fails to explicitly teach wherein the evaluation parameters are weighted for scoring purposes. However, examiner takes OFFICIAL NOTICE that weighting examination parameters is extremely old and well known in the art. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention, to utilize weighted scoring in the system of Gillio, in order to provide a score that emphasizes the more important portions of the examination more heavily.

Regarding claim 21, Gillio discloses evaluating user performance as described with reference to claim 17 above. Although Gillio fails to explicitly teach of calculation of a z-score for the parameters, applicant has admitted that computation of a z-score is old and well known to one of ordinary skill in the art (as stated in paragraph 0051 of the specification). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention, to utilize the statistical tool of a z-score in the system of Gillio, in order to provide an improved statistical mechanism for evaluating the performance of a user.

Claims 3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillio (US 5,704,791) in view of Pugh (US 2003/0031993) and also in view of Damadian (U.S. 6,544,041).

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Regarding claims 3 and 15, Gillio/Pugh disclose all of the features of parent claims 1 and 12 above, but fails to teach wherein the tracking mechanisms include Hall effect sensors. However, Damadian teaches of a surgical simulation system that tracks position of the surgical probe via the use of Hall effect sensors. See col. 6: 23-33. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the Hall effect sensor tracking of Damadian in the system of Gillio/Pugh, in order to provide a tracking system that does not involve moving parts that are more susceptible to wear and maintenance issues.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gillio (US 5,704,791) in view of Pugh (US 2003/0031993) and also in view of Younker (U.S. 5,620,326).

Regarding claim 10, Gillio/Pugh discloses all the features of parent claims 1 and 8 as described above, but fails to explicitly teach wherein the training objects include simulated skin. However, Younker discloses a surgical training device, wherein the training models include an outer layer of skin. See col. 7: 15-25. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the realistic training packs of Younker in the system of Gillio/Pugh, in order to provide more realistic haptic feedback for the user of the simulation system.

Response to Arguments

Applicant's arguments dated 5/29/2008 have been fully considered. In the previous rejection, examiner misstated that the Gillio reference does not teach processing position information of the instrument to objectively compare the information to a performance by an expert. Gillio does teach instrument tracking, as is clearly described in col. 13: 30-40. What Gillio does not teach is comparing the procedure data to an expert. In light of this error, this action is made NON_FINAL. Thus, Pugh corrects this shortcoming of Gillio as described above in regard to claim 1. Applicant's arguments that Pugh does not have the instrument are no longer relevant. Additionally, applicant's arguments that Pugh is not relevant art are not persuasive, because Pugh falls clearly in the medical simulation art, and with or without instruments,

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certain teachings of analyzing gathered performance data would be obvious across the medical simulation art. The question of success is not relevant, because examiner has extracted *only* the teaching of comparing student performance data to expert procedures, and not the actual physical constraints of Pugh. Similarly, the only teaching extracted from Damadian (also squarely in the medical simulation art) is of using Hall effect sensors to detect position of an instrument. Gillio discloses various methods to detect the position of the instrument as described in col. 10: 42-53. Hall effect sensors for position tracking, as taught by Damadian, are a viable alternative for position tracking. Examiner disagrees with applicant's assertion that Damadian is not relevant art. Both Damadian and the instant invention are surgical training systems. While applicant's submitted reference pertaining to the foam creation is enlightening and examiner does not argue any points therein, it is nonetheless true that Younker discloses using skin on the *anatomical models* as described in col. 7: 15-25. Applicants arguments about calculating a score are not persuasive, because Gillio discloses in col. 18: 25-40 wherein the questions require the user to "go through the virtual image data in a particular manner using the scope ... and can determine whether or not the test taker is correctly performing the operation". Gillio discloses in the same citation wherein feedback is provided relating to the performance. It would not be possible to provide feedback about the user *performance* without a basis for comparison, which in fact Gillio discloses in the same citation. While an explicit *numerical* score is not disclosed, some manner of evaluation must be used in order to make the comparison, and this evaluation would be a form of scoring. Col. 3: 5-10 and also col. 13: 40-50 also disclose wherein the user is evaluated based on position information.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy Musselman whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. M./
Acting Examiner of Art Unit 3714

/Robert E Pezzuto/
Supervisory Primary Examiner
Art Unit 3714